510(k) Summary

APR - 1 2008

Submitter Information
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Date summary prepared: February 18, 2008

Device Trade or Proprietary Names: ADVIA® Chemistry C-Reactive Protein_2 (CRP_2) Assay
ADVIA® Chemistry C-Reactive Protein_2 Calibrators

Device Common/Usual Name or Classification Name: C-Reactive Protein immunological test system Calibrators

Classification Number/Class: DCN / Class II
JIX / Class II

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: k072658

Assay Predicate Device:

	Predicate Device
Device Name	ADVIA® Chemistry Systems C-Reactive Protein
Common name	C-Reactive Protein Immunological Test System
510(k) Number	k992662
Manufacturer	Siemens Healthcare Diagnostics (formerly Siemens Medical Solutions Diagnostics / Bayer HealthCare LLC)

Calibrator Predicate Device:

	Predicate Device
Device Name	ADVIA Chemistry wrCRP Calibrators
Common name	C-Reactive Protein
510(k) Number	K022682 (Randox Labs, Ltd)
Manufacturer	Siemens Medical Solutions Diagnostics (formerly Bayer HealthCare LLC)

Device Description:

The ADVIA Chemistry C-Reactive Protein_2 (CRP_2) assay is for *in vitro* diagnostic use in the quantitative determination of the concentration of C-Reactive Protein in human serum and plasma on the ADVIA® Chemistry systems. The ADVIA Chemistry C-Reactive Protein_2 Calibrators are used to calibrate this method. The proposed labeling indicates the ADVIA Chemistry CRP_2 reagents and Calibrators are for use on the family of ADVIA Chemistry Systems (1200 / 1650 / 1800 / 2400).

The CRP_2 latex reagent is a suspension of uniform polystyrene latex particles coated with rabbit anti-CRP antibody. When serum or plasma containing CRP is mixed with the latex reagent, agglutination takes place resulting in an increase in the turbidity. This turbidity is measured at 571 nm. The CRP concentration in serum or plasma is determined from a calibration curve that is generated with the calibrators.

The ADVIA® Chemistry C-Reactive Protein_2 Calibrators consist of six (6) levels of protein stabilized matrices containing varying concentrations of recombinant human CRP. The Calibrators have targeted expected values (lot specific) of 0, 5, 20, 40, 160, and 320 mg/L.

The calibrators (1 mL/vial) are liquid and ready to use. Storage is at 2 - 8°C.

Statement of Intended Use:

The ADVIA Chemistry C-Reactive Protein_2 assay is for *in vitro* diagnostic use in the quantitative determination of the concentration of C-Reactive Protein in human serum and plasma (lithium heparin) on the ADVIA® Chemistry systems. Such measurements are used in the evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. Increases in CRP values are non-specific for many disease processes and should not be interpreted without a complete clinical evaluation.

The ADVIA Chemistry C-Reactive Protein_2 Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry Systems for the ADVIA Chemistry C-Reactive Protein_2 (CRP_2) method.

Comparisons to the Predicate Devices:

Assay Similarities

	ADVIA Chemistry C-Reactive Protein_2 (CRP_2) ***(new device)***	ADVIA Chemistry C-Reactive Protein (CRP) ***(predicate device)***
Intended Use	Quantitative determination of C-Reactive Protein	Quantitative determination of C-Reactive Protein
Specimen Type	Human serum or plasma (lithium heparin)	Human serum
Calibration	Multi-point (6)	Multi-point (6)
Reaction Type	Turbidimetric Endpoint	Turbidimetric Endpoint
Reagents	Two liquid reagents, ready to use	Two liquid reagents, ready to use
Standardization	CRM-470	CRM-470

Assay Differences

	ADVIA Chemistry C-Reactive Protein_2 (CRP_2) ***(new device)***	ADVIA Chemistry C-Reactive Protein (CRP) ***(predicate device)***
Assay Principle	Latex turbidimetric immunoassay	Polyethylene glycol assisted turbidimetric immunoassay
Read Wavelength	571 nm	340/ 694 nm
Calibrators	ADVIA Chemistry CRP_2 Calibrators	ADVIA Chemistry CRP Calibrators
Analytical Range (mg/L)*	4 to Calibrator 6 (Cal 6 target 304– 336)	5 to Calibrator 6 (Cal 6 target 195 – 205)
Expected Values	<10 mg/L**	<10 mg/L**

**Tietz NW. *Clinical Guide to Laboratory Tests, 4th Edition*

Calibrator Similarities

	ADVIA Chemistry C-Reactive Protein_2 Calibrators ***(new device)***	ADVIA Chemistry Wide Range C-Reactive Protein Calibrators ***(predicate device)***
Intended Use	For *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the CRP_2 method	For *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the wrCRP method
Matrix	Liquid, ready to use	Liquid, ready to use
Calibrator Levels	6	6
Calibrator Ingredients	Recombinant human CRP in a stabilized protein matrix; contains sodium azide	Recombinant human CRP in a stabilized protein matrix; contains sodium azide
Shelf Life	18 months	18 months
Standardization	CRM-470	CRM-470

Calibrator Differences

	ADVIA Chemistry C-Reactive Protein_2 Calibrators *(new device)*	ADVIA Chemistry Wide Range C-Reactive Protein Calibrators *(predicate device)*
Expected Values	Lot specific: **0, 5, 20, 40, 160, and 320 mg/L**	Lot specific: **0, 2.5, 10, 20, 80, and 160 mg/L**
Open Vial (capped) Stability	60 days stored @2-8°C	28 days stored @2-8°C

Performance:

Substantial equivalence was demonstrated by testing several performance characteristics including imprecision, method comparison, interfering substances, serum/plasma equivalency, and analytical range. The following tables summarize the precision (total), interfering substances, analytical range, and method comparison results.

All of the evaluation studies gave acceptable results compared to the predicate devices. These studies support that the ADVIA Chemistry C-Reactive Protein_2 assay is substantially equivalent to the ADVIA Chemistry C-Reactive Protein assay that is currently marketed.

Imprecision

ADVIA Chemistry C-Reactive Protein_2		**ADVIA Chemistry C-Reactive Protein**	
ADVIA 1650		ADVIA 1650	
Level (mg/L)	Total CV (%)	Level (mg/L)	Total CV (%)
31	1.3	5	13.6
56	1.1	42	4.6
83	1.5		
221	1.5		

Correlation

(y = ADVIA Chemistry C-Reactive Protein_2, x = comparison method/system)

Specimen type, System (y)	Comparison System (x)	N	Regression Equation	Sy.x (mg/L)	r	Sample Range (mg/L)
Serum, ADVIA 1650	ADVIA 1650 CRP	47	Y = 0.99x – 2.8	9.8	0.990	5 – 199

Interfering Substances (ADVIA Chemistry C-Reactive Protein_2 on ADVIA 1650)

Interfering Substance	Interferent Conc. (mg/dL)	CRP conc. (mg/L)	Effect (% change)
Hemoglobin	1000 mg/dL	5	0.7
Lipids (Intralipid)	1000 mg/dL	5	- 0.7
Lipids (Triglycerides)	1000 mg/dL	5	0.5
Bilirubin, free	60 mg/dL	5	1.8
Bilirubin, conjugated	60 mg/dL	5	2.0
Rheumatoid Factor	200 IU/mL	4	8.4

Analytical Range – Serum/Plasma

Platform	ADVIA Chemistry C-Reactive Protein_2
ADVIA 1650	4 to Calibrator 6 (304– 336) mg/L

Conclusions:

The ADVIA Chemistry C-Reactive Protein_2 assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Siemens Healthcare Diagnostics (formerly Bayer HealthCare LLC) ADVIA Chemistry C-Reactive Protein (k992662) assay.

The ADVIA® Chemistry C-Reactive Protein _2 Calibrators are substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed ADVIA Chemistry Wide Range C-Reactive Protein Calibrators (k022682).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Siemens Medical Solutions Diagnostics
c/o Philip Liu, Ph.D.
Manager, Regulatory Affairs and Compliance
511 Benedict Avenue
Tarrytown, NY 10591

Re: k072658
Trade/Device Name: ADVIA® Chemistry C-Reactive Protein_2 (CRP_2) Assay
ADVIA® Chemistry C-Reactive Protein_2 Calibrators
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN, JIX
Dated: February 19, 2008
Received: February 21, 2008

Dear Dr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k072658

Device Name: ADVIA CHEMISTRY C-Reactive Protein_2 Assay
ADVIA CHEMISTRY C-Reactive Protein_2 Calibrators

Indications For Use:

The ADVIA CHEMISTRY C-Reactive Protein_2 assay is for *in vitro* diagnostic use in the quantitative determination of the concentration of C-Reactive Protein (CRP) in human serum and plasma (lithium heparin) on the ADVIA Chemistry systems. Such measurements are used in the evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. Increases in CRP values are non-specific for many disease processes and should not be interpreted without a complete clinical evaluation.

The ADVIA Chemistry C-Reactive Protein_2 Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the C-Reactive Protein_2 (CRP_2) method.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K072658